



Driving progress
through partnership

Rizwan A. Qureshi

Direct Phone: +1 202 414 9218

Email: rqureshi@reedsmith.com

Reed Smith LLP
1301 K Street, N.W.
Suite 1000 - East Tower
Washington, D.C. 20005-3373
+1 202 414 9200
Fax +1 202 414 9299
reedsmith.com

August 1, 2024

Via ECF

The Honorable Arun Subramanian
United States District Judge
Southern District of New York
500 Pearl Street
New York, New York 10007

RE: U.S. Compounding Inc. Sentencing Submission – *United States of America v. US Compounding, Inc.*, 24-cr-00423

Dear Judge Subramanian:

This letter is submitted on behalf of U.S. Compounding Inc. (“USC”) in advance of its sentencing, which is scheduled for August 15, 2024. On July 9, 2024, USC, through its corporate representative, appeared before Your Honor and, pursuant to a written agreement (the “Plea Agreement”) with the U.S. Attorney’s Office for the Southern District of New York (the “Office” or the “Government”), pled guilty to a two-count criminal Information charging USC with mail fraud conspiracy, in violation of 18 U.S.C. § 1349, and conspiracy to commit drug adulteration and misbranding, in violation of 18 U.S.C. § 371. Although not binding on the Court, under the Plea Agreement USC has agreed that it is subject to a \$4,239,778 forfeiture payment and a criminal fine in the range of \$10,200,000 to \$16,959,112. For the reasons discussed below, USC respectfully requests that should the Court find that the imposition of a fine is necessary or appropriate, a fine no greater than the low-end of the agreed-upon range, \$10,200,000, in addition to the forfeiture payment it has already agreed to pay, would be sufficient and not greater than necessary to comply with 18 U.S.C. § 3553(a) (“Section 3553(a)”) and 18 U.S.C. § 3572(a) (“Section 3572(a)”).

I. Sentencing Court Considerations

Section 3553(a) outlines the procedures a sentencing court must consider in determining a sentence which is “sufficient, but not greater than necessary, to comply with the purposes set forth in paragraph 2.” Section 3553(a)(2) states that these purposes are:

(A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense;

(B) to afford adequate deterrence to criminal conduct;

(C) to protect the public from further crimes of the defendant; and

August 1, 2024
Page 2

(D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.

The sentencing court must also consult factors listed in Section 3572(a).

II. Should the Court Find That a Fine Is Necessary, an Analysis of Section 3553(a) Weighs Heavily in Favor of This Court Imposing a Fine Amount On the Low-End of the Range Agreed to by the Parties¹

Under Section 3553(a), the Court is required to consider the following factors in making its sentence determination: the nature and circumstances of the offense and the history and characteristics of the defendant; the need for the sentence imposed; the kinds of sentence and the sentencing range established in the Sentencing Guidelines; pertinent policy statements issued by the Sentencing Commission; the need to avoid unwarranted sentence disparities among similarly situated defendants; and the need to provide restitution to any victims of the offense. *See* 18 U.S.C. § 3553(a).

A. The Nature of the Offense and the Current Circumstances of USC Weigh Heavily in Favor of Imposing the Lowest Possible Criminal Fine Amount

First, the Court must evaluate “the nature and circumstances of the offense and the history and characteristics of the defendant.” 18 U.S.C. § 3553(a)(1).

1. USC’s Background

In March 2016, Adamis Pharmaceuticals Corporation (“Adamis”) acquired USC, a privately-held drug compounding company based in Arkansas that supplied prescription medications and compounded drugs intended for both human and animal use. At the time, Adamis was a publicly-traded biopharmaceutical company based in California. Founded in 2006, Adamis was focused on the development of therapeutic drugs for humans, including Zimhi, an opioid overdose treatment, and Symjepi, an emergency treatment of acute allergic reactions. After the acquisition, USC largely operated as an autonomous division of Adamis, and the human-side of the business routinely generated the bulk of the subsidiary’s revenue.

In 2021, due largely to the instant investigation by the Government (the “Investigation”), the Audit Committee of Adamis’s Board of Directors (the “Audit Committee”) directed Adamis to divest of the USC business and thus sold all USC assets, and ceased all USC operations. At this time, Adamis attempted to refocus on being a small, research and development firm.

However, due in part to difficult financial circumstances, in May 2023, Adamis merged with DMK Pharmaceuticals Corporation (“DMK” or the “Company”). On September 6, 2023, Adamis publicly announced that it had changed its name to DMK Pharmaceuticals Corporation.

¹ The fifth Section 3553(a) factor which requires the Court to evaluate “any pertinent policy statement . . . issued by the Sentencing Commission,” and the seventh Section 3553(a) factor, which requires the Court to evaluate “the need to provide restitution to any victims of the offense,” are not applicable here. 18 U.S.C. §§ 3553(a)(5), (7).

August 1, 2024
Page 3

Despite the merger, DMK continued to suffer financially, and ultimately filed for bankruptcy on February 2, 2024, in the U.S. Bankruptcy Court for the District of Delaware. On June 27, 2024, DMK ceased all operations, which included the resignation of all officers and members of the Board of Directors. Despite DMK's current circumstances, the last act of its parent company's Board of Directors was to authorize the undersigned as a corporate representative to effectuate the instant criminal disposition, accept responsibility on behalf of USC, and to resolve this yearslong matter.²

Although USC only recently pled guilty, USC first accepted responsibility in October 2021 – on its own volition and without any request from the Government – for the conduct at issue in this matter before the Arkansas Board of Pharmacy. USC entered into a consent order before the Arkansas State Board of Pharmacy (the “Consent Order”) in which it admitted, in relevant part, that it “failed to ensure prescribing veterinarians were licensed in the state into which product was ordered and/or shipped,” “provided remuneration directly to a veterinarian in connection with a veterinary prescription,” “provided veterinary prescription drugs to animal owners without the authorization of a licensed veterinarian and a prescription,” and “filled veterinary prescriptions for patients that did not have a valid practitioner-patient relationship.” *See Exhibit A.* The Consent Order resulted in USC surrendering its licenses effective October 31, 2021, paying a civil penalty of \$75,000, becoming ineligible for future licensure as a pharmacy or wholesale distributor in the state, and agreeing to pay investigative costs of \$75,000. *Id.*

2. Nature of Offense

The conduct at issue occurred in USC's veterinary division from 2015 through 2021. Beginning in approximately 2015, while USC was still a privately held corporation, several individuals at USC, including a former USC executive, and a Kentucky-based veterinarian (the “Veterinarian”) engaged in a prescription scheme where the Veterinarian's state veterinary licenses were used to generate prescriptions for the sale of omeprazole fenbendazole oral paste without there being a legitimate doctor-patient relationship with all equine patients. The omeprazole fenbendazole product is an equine drug used for treating ulcers, and the Veterinarian was licensed in six states at the time of his involvement in the scheme. Following Adamis's acquisition of USC, the Veterinarian entered into a consulting agreement, which Adamis's internal investigation revealed was used to conceal kickbacks paid to the veterinarian as part of the scheme. Upon information and belief, no horses were harmed as a result of the equine drug that was distributed as part of the scheme.

B. Should the Court Find a Fine is Necessary or Appropriate, a Fine of \$10,200,000 Achieves the Objectives of Section 3553(a)(2)

Next, the Court must consider “the need for the sentence imposed (A) to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; (B) to afford adequate deterrence to criminal conduct; (C) to protect the public from further crimes of the defendant; and (D) to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner.” 18 U.S.C. § 3553(a)(2).

² Although the instant proceeding would effectively resolve the Office's Investigation, the Company is in the final stages of accepting responsibility and resolving a parallel investigation with the U.S. Securities and Exchange Commission (“SEC”).

August 1, 2024
Page 4

Here, the Court need not impose a fine greater than \$10,200,000 on USC. USC ceased all operations in 2021, and not a single person involved in the conduct remains at USC's parent company, DMK. Adamis swiftly terminated all employees who may have been involved in the conduct or who refused to cooperate with its internal investigation into the conduct back in 2021. For the avoidance of doubt, upon merging with Adamis in 2023, DMK immediately appointed a new Chief Executive Officer, changed its name to DMK Pharmaceuticals Corporation, and appointed a new Chief Financial Officer, General Counsel and Corporate Secretary. While USC acknowledges its culpability in the criminal scheme, the imposition of a criminal fine greater than \$10,200,000 is not necessary to ensure just punishment for the offense, protect the public from further crimes of USC, or provide USC with needed training or correctional treatment.

The need for a high-end criminal fine is even further obviated by the fact that DMK has ceased all operations with no prospect for a reorganization and is currently in bankruptcy proceedings in which the Government has agreed that any criminal fine amount would be subordinated to all other general unsecured claims. *See Exhibit B*. Therefore, Section 3553(a)(2), weighs in favor of this Court imposing the low-end of the fine range, \$10,200,000. To the extent this Court believes further punishment for the offense may be needed to effect the purpose of Section 3553(a)(2), the ultimate resolution of the related indictment against a former USC executive should be sufficient to serve this purpose.

C. USC's Commitment to Cooperation and Remedial Measures Warrant the Lowest Criminal Fine Amount Under the Applicable Sentencing Range

Next, the Court must consider "the kinds of sentences available," and discuss "the sentencing range established for . . . the applicable category of offense committed by the applicable category of defendant as set forth in the guidelines[.]" *Id.* § 3553(a)(3)-(4).

Per the Plea Agreement, the parties agree that the applicable fine range yields a base offense level of 7 and total offense level of 27 based on U.S.S.G. §§ 2B1.1(a) and (b)(1)(J). USC has already agreed to the entry of a forfeiture money judgment in the amount of \$4,239,778 and to pay the mandatory special assessment of \$800. Therefore, the only aspect of the sentence that is at issue before the Court is the appropriate criminal fine amount to be paid by USC, which the parties agree is no less than \$10,200,000 and no more than \$16,959,112. USC maintains that its cooperation with the Office's Investigation, and the remedial measures that it undertook warrant the low-end of the criminal fine amount prescribed by the applicable sentencing range.

1. USC And Its Parent Company Have Been Committed to Cooperation Since Becoming Aware of the Investigation

Since becoming aware of the Office's Investigation, USC has exhibited complete cooperation with the Government and demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

On May 11, 2021, at the direction of the Audit Committee, Reed Smith LLP was authorized to accept service of two identical grand jury subpoenas, directed at Adamis and USC. That same day, the Audit Committee directed Reed Smith LLP to conduct an independent internal investigation to identify any

August 1, 2024
Page 5

potential evidence of criminal conduct or corporate fraud and to provide recommendations on remedial measures.

In part, Reed Smith LLP collected over 1.5 million documents from Adamis and USC personnel, interviewed 22 current or former Adamis and USC employees, engaged FTI Consulting to conduct an independent forensic analysis of Adamis's and USC's financial records related to the Veterinarian and USC's veterinary practices, and made 21 productions consisting of over 60,000 documents to the Government. In addition to its fulsome response to the grand jury subpoenas, Adamis affirmatively provided the Office with all relevant facts known to it regarding its investigation, including information about the individuals involved in the conduct described in the Plea Agreement – one of whom was charged in a related indictment on July 9, 2024.

Specifically, on September 28, 2021, Adamis proactively and voluntarily shared the findings of its investigation with the Government at a meeting at their offices. On April 8, 2022, Adamis made a Filip factor presentation to the Government, and had calls with the Government in June, September, October and December 2022 to answer follow-up questions from the Filip factor presentation and to provide other pertinent information that had become available. On February 22, 2023, and June 8, 2023, Adamis made presentations to the Government related to its proposed resolution of the matter, which included a discussion of Adamis's inability to pay. In addition to these more formal presentations, Adamis has maintained an open-line of communication with the prosecutors leading the Investigation, and has had routine phone calls with the Office since the inception of this matter dating back to 2021. On a parallel track, the Company has been cooperating with the related SEC investigation, including responding to voluntary document requests, sharing its investigative findings, and making its forensic accounting experts available to the SEC staff.

After several years of complete cooperation with both the Office and the SEC, in 2024, the Company's financial situation became untenable, and the Company filed for bankruptcy. Despite the Company's financial constraints, cooperation with the Government remained a priority of the Audit Committee, and Adamis has continued to update the Government of the status of the bankruptcy proceedings and has proactively worked towards a resolution of the instant matter, which includes a negotiated stipulation relating to the financial components of the Plea Agreement as reflected in **Exhibit B**.

2. USC and Its Parent Company Undertook Considerable Remedial Efforts

USC, through its parent company, has also implemented considerable remedial measures that support the Court's imposition of the lowest criminal fine amount. In 2021, Adamis sold all USC assets and ceased all USC operations. Adamis also promptly terminated all employees, including senior personnel, who may have been involved in the conduct at issue or who refused to cooperate in Adamis's investigation of the conduct. By 2022, Adamis was operating under new corporate leadership and several independent directors, including those with compliance experience, were added to Adamis's Board of Directors. Then, in 2023, Adamis merged with DMK Pharmaceuticals Corporation and again appointed new corporate leadership, ensuring that the Company was even further removed from those involved in the conduct at issue.

August 1, 2024
Page 6

In addition to a complete personnel overhaul, Adamis retained Reed Smith LLP and FTI Consulting and invested over \$250,000 in a cross-company enterprise risk assessment evaluating governance, product services, internal audit, risk management, compliance, and operations and implementing and effectuating the resulting recommendations. This risk assessment further demonstrated DMK's commitment to promoting and fostering a culture of compliance.

D. The Lowest Criminal Fine Amount Is Consistent with Sentences Among Similarly Situated Defendants

The court must also consider “the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct.” 18 U.S.C. § 3553(a)(6). Here, should the Court determine a fine is necessary or appropriate, a review of similarly situated defendants confirms that a criminal fine amount of \$10,200,000 is warranted.

In 2020, Animal Health International Inc. (“Animal Health”), a Colorado corporation that distributes prescription drugs for animals pled guilty to introducing and causing the introduction and delivery into interstate commerce misbranded veterinary prescription drugs, and Patterson Companies, Inc., Animal Health's corporate parent, entered into a non-prosecution agreement. *See* Press Release, U.S. Atty's Off. SDNY, *Animal Health International Sentenced on Federal Misbranding Charge* (May 4, 2020), <https://www.justice.gov/usao-wdva/pr/animal-health-international-sentenced-federal-misbranding-charge>. On May 4, 2020, Animal Health was ordered to pay a forfeiture money judgment of over \$46 million, \$1 million to the Virginia Department of Health Professionals, and a \$5 million fine. *Id.* Here, USC has similarly admitted to the misbranding of veterinarian prescription drugs but to a much lesser extent as it acquired over \$40 million less in assets than Animal Health as a result of its conduct. Importantly, Animal Health was only required to pay a \$5 million fine, which is less than half of the low-end of the criminal fine range agreed to by the parties.

Similar criminal fine amounts have been imposed in cases that are far more egregious than the conduct at issue here. For example, in April 2019, the United States Attorney for the Southern District of New York charged Rochester Drug Co-Operative, Inc. (“RDC”), one of the ten largest pharmaceutical distributors in the United States and two former executives, for unlawfully distributing oxycodone and fentanyl, and conspiring to defraud the U.S. Drug Enforcement Administration. The Office also filed a lawsuit against RDC for its knowing failure to comply with its legal obligation to report thousands of suspicious orders of controlled substances to the DEA. *See* Press Release, U.S. Atty's Off. SDNY, *Manhattan U.S. Attorney And DEA Announce Charges Against Rochester Drug Co-Operative And Two Executives For Unlawfully Distributing Controlled Substances* (Apr. 23, 2019), <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-and-dea-announce-charges-against-rochester-drug-co-operative-and>. RDC entered into a deferred prosecution agreement under which it agreed to accept responsibility for its conduct by making admissions and stipulating to the accuracy of an extensive Statement of Facts, pay a \$20 million penalty, reform and enhance its Controlled Substances Act compliance program, and submit to supervision by an independent monitor. Notably, the \$20 million penalty was the stipulated forfeiture amount, presumably encompassing the forfeiture amount along with the criminal fine. If USC was sentenced to pay a criminal fine on the high-end of the sentence range (\$16,959.112) along with its \$4,239,778 forfeiture payment, it would be paying a higher monetary penalty for its conduct than RDC paid for its role in distribution of

August 1, 2024
Page 7

oxycodone and fentanyl. While USC acknowledges its culpability, requiring it to pay anything more than the low-end of the criminal fine amount would be inconsistent with the agreement reached with RDC or with justice.

III. An Analysis of Section 3572(a) Also Weighs Heavily in Favor of This Court Imposing a Fine Amount on the Low-End of the Range Agreed to by the Parties

The sentencing court must, in addition to considering the Section 3553(a) factors, consult other factors listed in Section 3572(a), including:

- (1) the defendant's income, earning capacity, and financial resources;
- (2) the burden that the fine will impose upon the defendant, any person who is financially dependent on the defendant, or any other person (including a government) that would be responsible for the welfare of any person financially dependent on the defendant, relative to the burden that alternative punishments would impose;
- (3) any pecuniary loss inflicted upon others as a result of the offense;
- (4) whether restitution is ordered or made and the amount of such restitution;
- (5) the need to deprive the defendant of illegally obtained gains from the offense;
- (6) the expected costs to the government of any imprisonment, supervised release, or probation component of the sentence;
- (7) whether the defendant can pass on to consumers or other persons the expense of the fine; and
- (8) if the defendant is an organization, the size of the organization and any measure taken by the organization to discipline any officer, director, employee, or agent of the organization responsible for the offense and to prevent a recurrence of such an offense

18 U.S.C. § 3572(a).

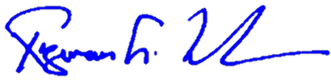
Here, an analysis of the relevant Section 3572(a) factors also weighs heavily in favor of the lowest possible fine amount being imposed on USC. DMK is in dire financial straits as it has filed for bankruptcy and for all intents and purposes is no longer operational. Any criminal fine amount would be recovered for pennies on the dollar from the Company's limited pool of assets and will not burden USC, but rather will have the unintended consequence of harming good faith creditors who believed in the medical benefits of Zimhi and Symjepi, among DMK's other medically beneficial products. Additionally, USC and its parent company took drastic measures to ensure that any and all persons involved in the underlying conduct at issue, or those who were not willing to cooperate in Adamis's internal investigation of the conduct, were terminated immediately. Notably, these disciplinary actions occurred in 2021, before the Company was made aware of its status as a target in the Office's Investigation. *See* § 3572(a)(8). Therefore, each factor of Section 3572(a) also weighs heavily in favor of the lowest possible fine amount.

August 1, 2024
Page 8

IV. Conclusion

For the foregoing reasons, USC respectfully submits that should the Court find that the imposition of a fine is necessary or appropriate, a fine no greater than the low-end of the agreed-upon range, \$10,200,000, in addition to the forfeiture payment it has already agreed to pay, would be sufficient and not greater than necessary to comply the factors in Sections 3553(a) or 3572(a).

Very truly yours,



Rizwan A. Qureshi